

PROCEDURE FOR OBTAINING AN *IN-STATE* or *OUT-OF-STATE* WATER BOTTLING PLANT LICENSE

License Application Form: DHS 8603

I. *IN-STATE* WATER BOTTLING PLANT LICENSE:

California Health and Safety Code (H&SC) Section 111120 requires that a bottler obtain a license issued by the Department of Health Services' Food and Drug Branch (FDB) to operate a water-bottling plant in California. The following describes what you must do to obtain your license:

LICENSE APPLICATION

Submit a fully completed application form with the required fee. You may call the FDB Water Licensing Desk at (916) 650-6515 to receive **Form DHS 8603** by mail, or download the form from the FDB website (<http://www.dhs.ca.gov/fdb/>; "Application Instructions and Forms").

Please make sure to write your firm name (If your check does not bear the firm name), license number (If the application is for renewal of your license), and the phrase "PCA Code 85125" on your check or money order. The fee is non-refundable.

The license is valid for one calendar year and expires on December 31. The business address must be that of the bottling plant, not the corporate headquarters. The mailing address can be either that of the plant, corporate headquarters or the firm's branch office (the license will be mailed to the mailing address). Any incomplete and/or illegible application will be RETURNED to the applicant.

FDB will perform an on-site inspection of the plant before issuing a license to assure that the bottling facility meets the requirements specified in Title 21 of the Code of Federal Regulations (21 CFR) Part 129, and other state and federal laws. Please contact one of the FDB offices (see the last page of this Procedure) for an appointment for inspection.

NOTE: Submit the information specified below (items 1, 2, 3 and 4) in duplicate to a Food and Drug Investigator at the time of inspection of your facility.

INFORMATION REQUIRED AT THE TIME OF INSPECTION

1. Water Source: All water sources must be identified on the application form. Only water from licensed sources or approved public drinking (or municipal) water districts can be processed for bottling.
 - a. If an unlicensed private well or spring source is the source of the water supply and the well or source is based and operated at the same location as the bottling plant, you must also submit a fully completed Private Water Source Operator's (PWSO) license application form with all required supporting documents and information as

specified in the "Procedure For Obtaining A Private Water Source Operator License." The license application fee for the PWSO license may be waived pursuant to H&SC Section 111120. Please contact the Water Licensing Desk (916-650-6515) to obtain the PWSO license application form, procedures and the list of substances to be analyzed.

- b. If the source is currently licensed for the sale of the particular water, provide the source information. The information must include the name of the source owner, a copy of the purchase contract, location of the source, license number and telephone number of the PWSO.
 - c. If the private water source is not currently licensed and is not located at the site of bottling plant, the owner of the source must submit a fully completed PWSO license application, application fee and required documents/information as indicated in the "Procedure for Obtaining a Private Water Source Operator License".
 - d. If public drinking (or municipal) water is used as a source, provide the name of the water district, address, telephone number, and a copy of the water district's most recent chemical, physical and microbiological analysis data for the water.
2. Analytical Tests Required (If you bottle more than one type of products at the facility, you must submit multiple sets of analysis for each product. Please contact Water Licensing Desk at 916-650-6515 for a copy of the list for substances to be analyzed):
- a. General chemical, physical, and radiological quality of water as required by the federal quality standards of bottled water and H&SC Sections 111080 and 111155 (see the attachment, Group I, II, III and V for specific substances). The test report should be valid for one year from the date of analysis.
 - b. Bacteriological quality of water as required by the federal quality standards of bottled water (Group IV).

NOTE: All testing must be done by a California certified water laboratory [Please contact the California Environmental Laboratory Accreditation Program at (510) 540-2800 for the list of locations/phone numbers of certified laboratories] or by a laboratory certified by the United States Environmental Protection Agency (USEPA). Testing done by a laboratory approved by the primary enforcement authority in states which have been granted primacy by the USEPA is also acceptable according to H&SC Section 111165.

3. Bottling Operation:

- a. Schematic site (facility) diagram;

- b. Schematic water treatment/bottling process diagram;
- c. Evidence (attach photographs) whether the facility has a separate bottling room in compliance with the requirement of 21 CFR 129.20(a);
- d. Evidence that the bottling room is operated in a sealed system under pressure;
- e. Specifications of equipment (please do not send copies of promotional material or advertisements; State on the top of the first page of each specification sheet whether the equipment has been approved for food and/or potable water use, and the name of the approval organization);
- f. Sanitation procedure;
- g. Information on your “unit package production code” as required by 21 CFR Part 129 (We suggest that a copy of your “recall plan,” which includes the production code information, be submitted);
- h. Information on your record keeping as required by 21 CFR Part 129 (We suggest that a copy of your “product quality control procedure,” which includes the record keeping information, be submitted);
- i. Photographs showing the bottling equipment and facility.

4. Labels and Promotional Materials:

Submit original labels and original advertising and promotional materials (original; not photocopies). Typed or photocopied labels may be submitted with prior approval of FDB only if the labels are: (1) printed or embossed directly on bottles, or (2) large labels (greater than 100 square inches in label size) and are printed directly on large boxes. Labels, advertising, and promotional materials must meet the requirements of H&SC Section 109875 et seq. and applicable federal regulations (including those for nutrition labeling if nutrient content or health claims are made or if nutrition information which necessitates nutrition labeling is provided).

5. After obtaining the license, you must do the following:

- a. Weekly coliform analysis: Your firm must test all product waters for total coliforms at least once every week. Maintain the original analysis report, and send a photocopy of the report to your local FDB office (call one of the FDB offices on Page 5 to get the address and phone number of the closest FDB office). The testing laboratory may send a copy of the test report directly to the local FDB office on your behalf. The laboratory must clearly identify your firm name, address, and license number on the report. You can obtain the list of certified laboratories near your location by calling DHS' Environmental Laboratory Accreditation Program (ELAP) at (510) 540-2800 or by visiting the following ELAP website:
<http://www.dhs.ca.gov/ps/ls/elap/html/LablistStart.htm>.

Take four samples for each product, and send all samples to the testing laboratory (the testing laboratory may sample directly, or ask you to take the samples

following its instruction for sample collection). The laboratory will randomly select one of the four samples (each product) and test for coliforms.

The laboratory can use the presence/absence (P&A) test for the coliform analysis.

Only negative (absence) test results are acceptable. If a sample tests positive (presence), you must resample the water (i.e., four random samples) within 24 hours and test using the multiple tube-fermentation method. If the test results show that the water contains more than 2.2 most probable numbers (MPN)/100 ml, you must immediately stop distributing the water; investigate the cause of the problem; take corrective actions; resample/test the water; and notify FDB Water Licensing Desk. You must not resume the distribution of water until the test shows that the water contains total coliforms of less than 2.2 MPN/100 ml.

- b. Annual Chemical-Physical-Radiological Analysis: Your firm must test each of your product waters for quality at least once every year. The list of substances to be analyzed is shown in a separate document (re: "List of Substances to be Analyzed"). You may call the FDB Water Licensing Desk at (916) 650-6615 to receive the list by mail, or download the list from the FDB website (<http://www.dhs.ca.gov/fdb/>; "Application Instructions and Forms"). You should maintain the original test result report, and send a photocopy of the report to your local FDB office. The testing laboratory may send a copy of the test data directly to the local FDB office on your behalf. The laboratory must clearly identify your firm name, address, and license number on the report. You can obtain the list of certified laboratories near your location by calling DHS' Environmental Laboratory Accreditation Program (ELAP) at (510) 540-2800 or by visiting the following ELAP website: <http://www.dhs.ca.gov/ps/ls/elap/html/LablistStart.htm>.

Take four samples for each product, and send all samples to the testing laboratory (the testing laboratory may take the samples directly, or ask you to take the samples following its sample collection instruction). The laboratory will make a composite of the 4 samples and test for the substances except for volatile organic chemicals (VOC's). For VOC's, the laboratory will randomly select one of the four samples (each product) and test for VOC's.

- c. Record keeping: You must keep all information/test data for at least for 2 years pursuant to the Title 21, Code of Federal Regulations, Section 129.80 (h). Refer to this Section regarding the types of information to be maintained.
- d. You must inform FDB when any changes are made in the bottling operation, design or construction of your plant, sanitary operation, equipment, water source, types of water produced, product labels, etc. You must also notify FDB if any of your products is recalled.

FOOD AND DRUG BRANCH OFFICES

FDB Food Safety Inspection Unit-Northern Region

100 Paseo de San Antonio, Room 304, San Jose, CA 95113
Telephone: (408)277-1832; Fax: (408) 277-1141

FDB Food Safety Inspection Unit-Southern Region

1449 West Temple Street, Room 224, Los Angeles, CA 90026
Telephone: (213) 580-5720; Fax: (213) 580-5750

II. OUT-OF-STATE WATER BOTTLING PLANT LICENSE:

California Health and Safety Code (H&SC) Sections 111120 and 111125 require that an out-of-state or a foreign bottler obtain a license issued by the California Department of Health Services' Food and Drug Branch (FDB) to sell or distribute bottled water products in California. The following describes what you must do to obtain your license.

1. Submit a completed application form with the required fee. You may call the FDB Water Licensing Desk at (916) 650-6515 to receive **Form DHS 8603** by mail, or download the form from the FDB website (<http://www.dhs.ca.gov/fdb/>; "Application Instructions and Forms").

Please write your firm name (If your check does not bear the firm name), license number (If the application is for renewal of your license), and the phrase "PCA Code 85125" on your check or money order. The fee is non-refundable.

The license is valid for one calendar year and expires on December 31. The business address must be that of the out-of-state bottling plant, not the corporate headquarters. The mailing address can be either that of the corporate headquarters or the firm's branch office (the license will be mailed to the mailing address). Any incomplete and/or illegible application will be RETURNED to the applicant, which would result in a significant delay in the processing of that application.

2. Submit copies of valid bottling plant and water source licenses, certificates or permits issued by the state or country agency which has jurisdiction over the out-of-state (or foreign) plant and water source.
3. Water Source:

If a private well or spring is the source of the water:

- a. Information from a Licensed (or Certified) Hydrogeologist, Geologist, Engineering Geologist or Hydrogeological Engineer:
 - 1) Description of the exact source location; and a detail map (if not available, a drawing) showing the boundary and the location of the natural spring (if applicable), bore hole (if applicable), well (if applicable), buildings, storage tank and piping.
 - 2) Review of the hydrogeology surrounding the site including a description of the vertical and horizontal extent of the source aquifer.

- 3) Information on the recharge area or zone of influence of the subject source, and documentation that identifies and evaluates actual and potential sources of contamination.
 - 4) Details of the source development: description and/or diagrams of the method of construction, collection and catchment of source water, storage facility, conveyance and loading systems, underground piping map and treatment systems used. All equipment must have documented proof that it has been approved for potable water use.
 - 5) If ground water (e.g., spring water, artesian well water, well water), evidence (e.g., microscopic particulate analysis) that it is not under the direct influence of surface water as defined in 40 CFR 141.2.
 - 6) Substantiating information that the designation of source water (e.g., "spring water", "artesian well water", "well water") meets the definition for the terms as specified in H&SC Section 111175 and 21 CFR Section 165.110(a).
- b. Information from the State, Local Health Agency, or Other Approval Authority:
- 1) Copies of well (borehole) driller's report and/or well (borehole) log; well (borehole) sealing diagram; certificate or permit for satisfactory well construction from the pertinent state or local agency.
 - 2) Sanitary appraisal report for the well or spring.
- c. If your source is a spring and the spring water is extracted from a bore hole(s) using external force, you must provide the following information as well:
- 1) An explanation why a borehole(s) is used;
 - 2) Evidence including actual data that: (1) water flows naturally to the surface of the earth at the natural spring (a copy of the inspection report from the pertinent government agency); (2) spring water collected from the bore hole is from the same underground stratum as the natural spring, as shown by a measurable hydraulic connection (using a hydrogeologically valid method such as the pumping test, dye test) between the bore hole and the natural spring; (3) water from the bore hole has all the physical properties, before treatment, and is of the same composition and quality as the water that flows naturally to the surface of the earth (i.e., natural spring).

d. Samples for Testing:

- 1) All testing must be done on samples collected after completion of the entire system (e.g., well drilling, piping, installation of storage tanks, loading system).
- 2) If multiple sources or multiple water extraction systems feed into a common distribution system (e.g., storage tank), only the sample from the common system (rather than from each source or each extraction system) can be tested, provided that the sources/extraction systems have already been approved. For a new license, however, each source (or each water extraction system) must be analyzed separately.

e. Photographs of the source showing its construction, surrounding area, storage facility, conveyance and loading systems, and treatment systems used.

If public or municipal water is used as a source:

Provide the name of the Water District, address, telephone number, and a copy of the Water District's most recent chemical, physical, radiological and microbiological analysis data for the water.

4. Testing of Source Water and Product Water:

(You must submit two sets of analysis, one for source water and another for product water. If you have multiple sources and/or multiple types of products to be bottled at the facility, you must submit a set of analysis for each source and each product. Please contact Water Licensing Desk at 916-650-6515 to receive the "list of substances to be analyzed" by mail, or download it from the FDB website (<http://www.dhs.ca.gov/fdb/>; "Application Instructions and Forms".)

- a. General chemical, physical, and radiological quality of water as required by the federal quality standards for bottled water and H&SC Sections 111080, 111150 and 111155 (Group I, II, III and V). The test results should be valid for one year from the date of analysis.
- b. Bacteriological quality of water as required by the federal quality standards of bottled water (Group IV).

NOTE: All testing must be done by a California certified water laboratory [Please contact the California Environmental Laboratory Accreditation Program at (510) 540-2800 for

the list of locations/phone numbers of certified laboratories] or by a laboratory certified by the United States Environmental Protection Agency (USEPA). Testing done by a laboratory approved by the primary enforcement authority in states which have been granted primacy by the USEPA are also acceptable pursuant to H&SC Section 111165.

5. Bottling Operation:

- a. Schematic site (facility) diagram;
 - b. Schematic water treatment/bottling process diagram;
 - c. Evidence (attach photographs) that the facility has a separate bottling room in compliance with the requirement of 21 CFR 129.20(a);
 - e. Evidence that the bottling room is operated in a sealed system under pressure;
 - f. Specifications of equipment (please do not send copies of promotional material or advertisements; State on the top of the first page of each specification sheet whether the equipment has been approved for food and/or potable water use, and the approval organization);
 - g. Sanitation procedures;
 - h. Information on your “unit package production code” as required by 21 CFR Part 129 (We suggest that a copy of your “recall plan,” which includes the production code, be submitted);
 - i. Information on your “record keeping” as required by 21 CFR Part 129 (We suggest that a copy of your “product quality control procedures,” which includes the record keeping information, be submitted);
 - j. Photographs showing the bottling equipment and facility.
6. Labels and Promotional Materials: Submit labels, advertising and promotional materials (original; not photocopies). Typed or photocopied labels may be submitted with prior approval of FDB only if the labels are: (1) printed or embossed directly on bottles, or (2) large labels (greater than 100 square inches in label size) that are printed directly on large boxes. Labels, advertising, and promotional materials must meet the requirements of H&SC Section 109875 et seq. and applicable federal regulations [including those of nutrition labeling if nutrient content or health claims are made or if nutrition information necessitates nutrition labeling is provided].

NOTE: Any new drilling or redeveloping of a source under this license will automatically trigger the revaluation of the source. You must contact us for reevaluation of the source and obtain an approval before using it.

7. After obtaining the license, you must do the following:

- a. Weekly coliform analysis: Your firm must test each source water and each product water for total coliforms at least once every week. Maintain the original test result report, and send a photocopy of the report to the FDB office on the last page of this Procedure. The testing laboratory may send a copy of the test report directly to the FDB office on your behalf. The laboratory must clearly identify your firm name, address, and license number on the report. .

Take four samples for each source water and each product water, and send all samples to the testing laboratory (the testing laboratory may sample directly, or ask you to take the samples following its instruction for sample collection). The laboratory will randomly select one of the four samples (for each source water and each product water), and test for coliforms.

The laboratory can use the presence/absence (P&A) test for the coliform analysis. Only negative (absence) test results are acceptable. If a sample tests positive (presence), you must resample the water (i.e., four random samples) within 24 hours and test using the multiple tube-fermentation method. If the test data shows that the water contains more than 2.2 most probable numbers (MPN)/100 ml, you must immediately stop distributing the water; investigate the cause of the problem; take corrective actions; resample/test the water; and notify FDB Water Licensing Desk. You must not resume the distribution of water until the test shows that the water contains total coliforms of less than 2.2 MPN/100 ml.

- b. Annual Chemical-Physical-Radiological Analysis: Your firm must test each source water and each product water for quality at least once every year (If your firm uses public drinking water as source water, you do not have to analyze the source water. Just provide a copy of the water analysis received from the public drinking water system). The list of substances to be analyzed is shown in a separate document (re: "List of Substances to be Analyzed"). You may call the FDB Water Licensing Desk at (916) 650-6615 to receive the list by mail, or download the list from the FDB website (<http://www.dhs.ca.gov/fdb/>; "Application Instructions and Forms"). You should maintain the original test result report, and send a photocopy of the report to the FDB office on Page 11. The testing laboratory may send a copy of the test data directly to the FDB office on your behalf. The laboratory must clearly identify your firm name, address, and license number on the report.
- c. Record keeping: You must keep all information/test data for at least for 2 years pursuant to the Title 21, Code of Federal Regulations, Section 129.80 (h). Refer to this section regarding the types of information to be kept.
- d. You must inform FDB when any changes are made in the bottling operation, design or construction of your plant, sanitary operation, equipment, water source, types of

water produced, product labels, etc. You must also notify FDB if any of your products are recalled.

FOOD AND DRUG BRANCH OFFICE

California Department of health services
Food and Drug Branch, Water Licensing Desk (MS 7602)
P.O. Box 997413
Sacramento, CA 95899-7413

(Revised 04/07/2004)